UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------|-------------|----------------------|-----------------------|------------------|
| 10/539,828 | 07/09/2007 | Francois Romagne | 1NN-122 | 5861 |
| | 7590 | EXAMINER | | |
| A PROFESSIONAL ASSOCIATION | | | BELYAVSKYI, MICHAIL A | |
| PO Box 142950 GAINESVILLE | | | ART UNIT | PAPER NUMBER |
| | | | 1644 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 02/26/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | | |
|--|---|-----------------------|--|--|--|--|--|
| Office Action Commence | 10/539,828 | ROMAGNE ET AL. | | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | |
| | Michail A. Belyavskyi | 1644 | | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | |
| Status | | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>23 Ja</u> | nuary 2009. | | | | | | |
| | _ | | | | | | |
| | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| | | | | | | | |
| Disposition of Claims | | | | | | | |
| | Claim(s) <u>28-42</u> is/are pending in the application. | | | | | | |
| | 4a) Of the above claim(s) <u>36-39</u> is/are withdrawn from consideration. | | | | | | |
| · | 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>28-35 and 40-42</u> is/are rejected. | | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | | |
| 8) Claim(s) are subject to restriction and/or | 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | | |
| 10)⊠ The drawing(s) filed on <u>30 July 2007</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | |
| * See the attached detailed Office action for a list of the statement (s) | <u> </u> | | | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>07/09/07</u>. | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ite | | | | | |
| | | | | | | | |

Application/Control Number: 10/539,828 Page 2

Art Unit: 1644

DETAILED ACTION

1. Applicant's amendment, filed 01/23/09 is acknowledged.

Claims 28-42 are pending.

Applicant's election without traverse of Group V, claims 28-31 in the reply filed on 01/23/09 is acknowledged.

2. Claims 36, 37, 38 and 39 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 28-35, 40-42 read on a method for stimulating the proliferation of NK cells comprising contacting NK with NCR antibody, wherein said antibody is anti-NKp46 antibody and a cytokine are under consideration in the instant application.

- 3. Claim 34 is objected because they do not correspond to the scope of the elected Group V, that reads on anti-NKp46 antibody. Appropriate correction is required.
- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Art Unit: 1644

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 28-35, 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sivori et al (Eur.J. Immunol, 1999, v.29, pages 1656-1666) in view of Carlens et al (IDS).

Sivori et al., teach the expression of novel activating NKp46 receptor on the cell surface of natural killer cells (NK) (see entire document, Abstract in particular). Sivori et al., teach that cross-linking of said receptors with antibody results in activation of said NK cells, (see overlapping pages 1676-1657 in particular).

Carlens et al., teach a method for stimulation of the proliferation of NK cells comprising contacting said cells with a composition comprising antibody to the surface activating receptor, such as anti- CD3 antibody and interleukin, such as IL2 (see entire document, Abstract in particular).

All the claimed elements were known in the prior art and one skill in the art could have combine the elements as claimed by known methods with no change in their respective function and the combination would have yield predictable results to one of ordinary skill in the art at the time of the invention (see KSR International Co v Teleflex Inc., 550U.S.-, 82 USPQ2d 1385, 2007).

Thus it would have been obvious to one of the ordinary skill in the art at the time the invention was made to combine anti-NKp46 antibody with IL2 for stimulating the proliferation of NK cells with a reasonable expectation of success because the prior art suggests the use of said substances for successful stimulation of NK cells. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205USPQ 1069, 1072 (CCPA 1980) (see MPEP 2144.06).

Claims 29 -31, and 41-42 are included because it would be conventional and within the skill of one in the art to determine: (i) the optimal ways and means of administering of said antibody and IL2; (ii) an effective amounts of antiNKp30 antibody and IL2 to be administered. Further, it has been held that where the general conditions of a claim are disclosed in the prior art,

Art Unit: 1644

discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results; In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930). See MPEP 2144.04 (section IV(C)).

The motivation need not be found in the references sought to be combined, but may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself. In re Dembiczak, 175 F.3d 994, 999 (Fed. Cir. 1999).

As explained in Motorola, Inc. v. Interdigital Tech. Corp., 121 F.3d 1461, 1472 (Fed. Cir. 1997), "there is no requirement that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art."

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571/272-0878.

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michail A Belyavskyi/ Primary Examiner, Art Unit 1644 Application/Control Number: 10/539,828

Art Unit: 1644

Page 5